SEP - 9 2003

SECTION 9: 510(K) SUMMARY

K030563

1. ***Summary Preparation Date:*** February 17, 2003

2. ***Applicant Information:***

Name: Hamilton Medical AG
Via Nova
CH-7403 Rhaezuens
Switzerland
FDA Establishment Registration Number: 3001421318
Contact Person: J. David Thompson, General Manager
Hamilton Medical, Inc.
PO Box 30008
Reno, NV 89502
775-858-3200 Fax: 775-856-5621
email: thompson@hammed1.com

3. ***Device Proprietary Name:*** ARABELLA® NCPAP Masks

Mask Sizes (Size #):
a. Small (0)
b. Medium (1)
c. Large (2)
Common/Usual Name: Infant Nasal CPAP Masks (Single-Patient Use Only)
Classification Name: Noncontinuous Ventilator Accessories
Classification Panel: Anesthesiology
Classification Code: BZD

4. ***BZD Device Identification:*** (per 21 CFR Part 868.5905): A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing. [The subject device is an accessory to a noncontinuous ventilator (FDA product code BZD.]

5. ***Regulatory Status:*** Noncontinuous ventilators and their accessories (FDA product code BZD) have been classified by the FDA as class II. There are currently no mandatory performance standards or special control requirements for any of these devices.

6. ***General Device Description:*** The ARABELLA® NCPAP Masks are single-patient use only infant nasal CPAP masks which can be used with the Hamilton ARABELLA tubing and support set (K945740) as an alternative to the NCPAP prongs. The tubing and support set has been designed to work with the ARABELLA Monitoring Oxygen/Air Mixer (K990293 and K960359). The items covered by K945740 and K990293/K960359 together form the Hamilton Medical ARABELLA infant NCPAP system.

7. ***Intended Use:*** The Hamilton Medical ARABELLA® NCPAP Masks (single patient use only) are intended for use with the Hamilton ARABELLA® infant nasal CPAP system which consists of (a.) the tubing and support set and (b.) the monitoring oxygen/air mixer. This system is intended to provide CPAP therapy with a nasal mask or nasal prongs in hospitals or other clinical settings to treat newborns and infants.

8. ***Device Materials***: The ARABELLA® NCPAP Masks are constructed of latex-free silicone rubber. This material has successfully undergone biocompatibility testing at a nationally recognized biological testing laboratory.

9. ***Substantial Equivalence:*** The Hamilton ARABELLA® NCPAP Masks are substantially equivalent to the SensorMedics/EME Infant Flow Nasal CPAP Mask (K984254/K011516).

   Among the information and data presented in the 510(k) submission to support the equivalency of the ARABELLA® NCPAP Masks to the predicate device are: (a.) device description, (b.) comparison to the legally marketed predicate device, (c.) human factors information, (d.) laboratory verification and validation testing of the device specifications, and (e.) comparison testing of NCPAP mask performance to NCPAP prong performance within the ARABELLA infant NCPAP system. The testing demonstrated compliance with the mask specifications and showed no difference in the performance, safety or effectiveness between the nasal masks and the nasal prongs.

10. ***Comparison Table***: The table that follows describes the important characteristics of the ARABELLA® NCPAP Masks and its predicate device: SensorMedics/EME Infant Flow Nasal CPAP Mask (K984254/K011516).

#	Characteristic	SensorMedics/EME Infant Flow Nasal CPAP Masks	Hamilton ARABELLA® NCPAP Masks
1	intended use	used with the SensorMedics/EME Infant Flow System, consisting of a Driver and NCPAP Generator; provides CPAP with a nasal mask; alternative to nasal prongs	used with the Hamilton ARABELLA® infant nasal cpap system which consists of (a.) the tubing and support set and (b.) the monitoring oxygen/air mixer; provides CPAP therapy with a nasal mask; alternative to nasal prongs
2	indications	for nasal cpap treatment of newborns and infants with RDS or who are recovering from RDS	for nasal cpap treatment newborns and infants
3	environment	for use in hospitals	for use in hospitals or other clinical settings
4	reuse	single-patient use only	single-patient use only
5	fastening means	mechanism identical to nasal prongs	mechanism identical to nasal prongs
6	mask sizes*	extra small and extra large	small (size 0), medium (size 1), and large (size 2)
7	mask material in contact with face	silicone rubber	latex-free silicone rubber
8	sterility at shipment	provided clean, non-sterile	provided clean, non-sterile
9	recommended service life	not specified	1 week maximum; change when uncleanable
10	treatment range	up to 9 cm H_2O	up to 7 cm H_2O
11	effective dead space	extra small: 0.6 ml. extra large: 1.1 ml.	small: 0.6 ml. large: 1.2 ml. medium: 1.1 ml.

*The extra small EME mask corresponds most closely to the small ARABELLA Mask; the extra large EME mask corresponds most closely to the medium ARABELLA Mask; the large ARABELLA Mask is for larger infants than are covered by the EME sizes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

Mr. David Thompson
Hamilton Medical Incorporated
P.O. Box 30008
Reno, Nevada 89502

Re: K030563
Trade/Device Name: Hamilton Medical ARABELLA NCPAP Masks
Regulation Number: 868.5905
Regulation Name: Non-Continuous Ventilator, Accessory
Regulatory Class: II
Product Code: BZD
Dated: June 12, 2003
Received: June 13, 2003

Dear Mr. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4:
INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K030563

Device Name: Hamilton Medical ARABELLA® NCPAP Masks

Indications For Use:

The Hamilton Medical ARABELLA® NCPAP Masks (single patient use only) are intended for use with the Hamilton ARABELLA® infant nasal CPAP system which consists of (a.) the tubing and support set and (b.) the monitoring oxygen/air mixer. This system is intended to provide CPAP therapy with a nasal mask or nasal prongs in hospitals or other clinical settings to treat newborns and infants.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

E Petrucelli for JXH 9/9/03

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030563

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)